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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/880,710	06/13/2001	Stavroula Kousteni	ANA 1007 US	5533
20786	7590	01/28/2005	EXAMINER	
KING & SPALDING LLP 191 PEACHTREE STREET, N.E. ATLANTA, GA 30303-1763			BASI, NIRMAL SINGH	
			ART UNIT	PAPER NUMBER
			1646	
DATE MAILED: 01/28/2005				

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 09/880,710	<b>Applicant(s)</b> Kousteni et al.	
	<b>Examiner</b> Nirmal S. Basi	<b>Art Unit</b> 1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 08 November 2004.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 8-10 and 16-36 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 8-10 and 16-36 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 08 November 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

1. Amendment filed 11/08/04 has been entered.
2. Drawings filed 11/8/04 have been approved by the Examiner.

#### ***Claim Rejections - 35 USC § 112, Second Paragraph***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 8-10, 16-36 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 8, 16, 27-36 are indefinite because it is not clear what is a selective nongenotropic effect so as to allow the metes and bounds of the claim to be determined. Applicant argues examples of nongenotropic effect are provided in the specification. Applicant's arguments have been fully considered but not found persuasive. It is still not clear what selective nongenotropic effect is being measured.

Claim 8 is indefinite because it is not clear what nongenotropic activity is mediated by the ligand-binding domain of the steroid receptor without substantially activating DNA-binding domain so as to allow the metes and bounds of the claim to be determined. Further it is not clear when a compound substantially activates as compared to not substantially activating. Also it is not clear when a genotropic effect is

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substantially induced as compared to not substantially induced. Applicant has not disclosed when a compound substantially activates as compared to not substantially activating. The term "substantially " in claim 8 is a relative term which renders the claim indefinite. The term "substantially " is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. Applicant has not provided a definition for a compound substantially activates or substantially induces.

Claim 8 is indefinite because it is not clear what biological activity is being measured or nongenotropic activity is mediated.

Claim 16 is indefinite because it not clear what is a "steroidal of activating nongenotropic activity" so as to allow the metes and bounds of the claim to be determined. Also, last paragraph of claim, it is not clear if both non-genotropic activity and transcriptional activity are less than 10%, or only the transcriptional activity is 10% of endogenous ligand. It is not clear what nongenotropic activity of the receptor is mediated.

Claim 18 is indefinite because it is not clear what is a signal transduction pathway, where does the pathway start and end so as to allow the metes and bounds of the claim to be determined. Further the transduction pathway is not an activity.

Claim 19 is indefinite because it is not clear what second messengers are considered non-genotropic activity so as to allow the metes and bounds of the claim to be determined. The second messenger system is not an activity.

Claims 20-22 is indefinite because it is not clear what are the specific kinase signal transduction pathway, where do the pathways start and end so as to allow the metes and bounds of the claim to be determined.

Claims 23, 27, 28 is indefinite because it is not clear when a compound induces a nongenotopic effect without substantially inducing a genotropic response so as to allow the metes and bounds of the claim to be determined. Further it is not clear when a compound substantially activates as compared to not substantially activating. The preamble of the claim does not disclose the goal of the claim; it is not clear what the compound is being evaluated for. It is not clear what non-genotropic effect is being measured

Claim 26 is indefinite because it is not clear what is the target gene.

Claim 27 is indefinite because it is not clear what compound are considered artificial or natural steroid receptors so as to allow the metes and bounds of the claim to be determined. Further it is not clear which compound identified by claimed method would treat steroid receptor related diseases or disorders, as compared to those compounds that provide a positive result in the method and have no use as therapeutic agents. Further it is not clear what diseases are considered steroid receptor related diseases, what relationship has to be present for said diseases to be considered steroid receptor related. Further it is not clear when a compound substantially activates as compared to not substantially activating. Applicant has not disclosed when a compound substantially activates as compared to not substantially activating. The term "substantially " in claim 27 is a relative term, which renders the claim indefinite. The

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term "substantially " is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. It is not clear what biological activity is being measured or nongenotropic activity is mediated.

Claim 28 is indefinite because it is not clear what compound are considered natural or artificial natural steroid receptors so as to allow the metes and bounds of the claim to be determined. Further it is not clear which compound identified by claimed method would treat steroid receptor related diseases or disorders, as compared to those compounds that provide a positive result in the method and have no use as therapeutic agents. Further it is not clear what diseases are considered steroid receptor related diseases, what relationship has to be present for said diseases to be considered steroid receptor related. Also it is not clear what is measured when the level of transcription is determined. What is a pro-apoptic agent? The term "substantially " in claim 28 is a relative term, which renders the claim indefinite. The term "substantially " is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

Claim 29 is indefinite because it is not clear what compound are considered artificial or natural steroid receptors so as to allow the metes and bounds of the claim to be determined. What is extra cellular regulated kinase activation and how is it determined? Also it is not clear what is measured when the level of transcription is

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determined. What are considered minimal transcriptional levels as compared with non-minimal levels?

Claim 30, 31 is indefinite because it is not clear what is a functional engineered of modified forms of steroid receptor so as to allow the metes and bounds of the claims to be determined. What function is required., what is the critical feature of the form relating structure to function. Said a modified forms encompass an infinite number of variants, it is not clear which variants would be considered modified form of the steroid receptor. It is not clear what is the signal transduction pathway responsive transcriptional control unit.. What signal is transduced by the control unit? Further, it is not clear what is transduction pathway, where does the pathways start and end so as to allow the metes and bounds of the claim to be determined. Also, what is the reporter gene, what does it report and how is it measured? It is not clear what biological activity is being measured or nongenotropic activity is mediated.

Claim 33 is indefinite because it is not clear what is measured when the amount of transcription is measured, what genotropic activity is so as to allow the metes and bounds of the claim to be determined. What is extracellular regulated kinase activation and how is it determined? It is not clear what biological activity is being measured or nongenotropic activity is mediated. The term "substantially " in claim 33 is a relative term, which renders the claim indefinite. The term "substantially " is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

Claim 35 is indefinite because it is not clear what is a genetic variant so as to allow the metes and bounds of the claim to be determined. Genetic variants encompass an infinite number of compounds. It is not clear what comprises a response element-reporter gene, serum response element reporter gene construct. Further it is not clear when a compound activates the transcription of the response element-reporter gene construct without substantially effecting the transcription of the response element reporter gene construct as compared to when a compound activates the transcription of the response element-reporter gene construct by substantially effecting the transcription of the response element reporter gene construct. The term "substantially " in claim 28 is a relative term which renders the claim indefinite. The term "substantially " is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

Claim 36 is indefinite because it is not clear what is a genetic variant so as to allow the metes and bounds of the claim to be determined. Genetic variants encompass an infinite number of compounds. It is not clear what comprises a response element-reporter gene, how is transcription determined, what is signal transduction pathway responsive transcriptional control unit, Further it is not clear when a compound activates the transcription of the second cell without substantially effecting the transcription of the first cell. The term "substantially " in claim 36 is a relative term, which renders the claim indefinite. The term "substantially " is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and



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one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

Claims 9, 10, 17, 24-26 and 34 are rejected for depending on an indefinite base claim.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nirmal S. Basi whose telephone number is 571-272-0868. The examiner can normally be reached on 9:00 AM-5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony C. Caputa can be reached on 571-272-0829. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Nirmal S. Basi *N SB*  
January 25, 2005

*Michael D. Pak*  
MICHAEL PAK  
PRIMARY EXAMINER